4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

[Docket No. FDA-2016-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July and August 2016. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of a sponsor's address.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July and August 2016, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required

under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During July and August 2016

Approval Date	File No.	Sponsor	Product Name	Species	Effect of the Action/Indications for Use	Public Documents
July 24, 2016	141-458	Merial, Inc., 3239 Satellite Blvd., bldg. 500, Duluth, GA 30096-4640	EQUIOXX (firocoxib) Tablets	Horses	Original approval for the control of pain and inflammation associated with osteoarthritis in horses.	FOI Summary
July 20, 2016	141-459	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	BRAVECTO (fluralaner topical solution) for Dogs BRAVECTO (fluralaner topical solution) for Cats	Dogs, cats	Original approval for killing adult fleas, for the treatment and prevention of flea infestations, and for the treatment and control of tick infestations in dogs and cats.	FOI Summary
August 12, 2016	141-461	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211	NOCITA (bupivacaine liposome injectable suspension)	Dogs	Original approval to provide local postoperative analgesia for cranial cruciate ligament surgery in dogs.	FOI Summary
July 1, 2016	200-501	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland	Praziquantel (praziquantel) Injection	Dogs	Original approval of a generic copy of NADA 111-607.	FOI Summary
August 5, 2016	200-508	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland	BILOVET (tylosin) Injection	Cattle, swine	Original approval of a generic copy of NADA 012-965.	FOI Summary

II. Change of Sponsor's Address

Nexcyon Pharmaceuticals, Inc., 644 West Washington Ave., Madison, WI 53719 has informed FDA that it has changed its address to P.O. Box 259158, Madison, WI 53725. Accordingly, the regulations at 21 CFR 510.600(c) will be amended to reflect this sponsor's change of address.

III. Technical Amendments

FDA has noticed that drug labeler codes (DLCs) in several sections of part 558 (21 CFR part 558) do not accurately reflect the sponsorship of a new animal drug application. At this time, we are amending part 558 to remove these DLCs. Also, FDA is amending the regulations to revise a human food safety warning for tulathromycin injectable solution in 21 CFR 522.2630 and to correct a cross-reference for combination medicated feeds in § 558.128 (21 CFR 558.128). These actions are being taken to improve the accuracy of the regulations.

The restrictions for veterinary feed directive (VFD) drugs in part 558 are being revised to reflect a uniform text. In addition, we are revising § 558.59 to reflect a current format. These actions are being taken to improve the clarity of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, 529, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Revise § 510.600 as follows:

a. In the table in paragraph (c)(1):

i. In the entries for "Cronus Pharma LLC", "HQ Specialty Pharma Corp.", "OXIS International, Inc.", "Pharmgate LLC ", "Putney, Inc.", "SmartVet USA, Inc.", and "Wildlife Laboratories, Inc.", remove "Suite" and in its place add "suite";

ii. In the entry for "Merial, Inc.", remove "Bldg." and in its place add "bldg.";

iii. In the entry for "Nexcyon Pharmaceuticals, Inc.", remove "644 West Washington Ave., Madison, WI 53719" and in its place add "P.O. Box 259158, Madison, WI 53725";

b. In the table in paragraph (c)(2):

i. In the entries for "024991", "026637", "042791", "053923", "069043", "069254", and "086001", remove "Suite" and in its place add "suite";

ii. In the entry for "050604", remove "Bldg." and in its place add "bldg."; and

iii. In the entry for "050929", remove "644 West Washington Ave., Madison, WI 53719" and in its place add "P.O. Box 259158, Madison, WI 53725".

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. In § 520.928, revise paragraph (c) to read as follows:

§ 520.928 Firocoxib tablets.

* * * * *

(c) Conditions of use--(1) Dogs--(i) Amount. 5 mg/kg (2.27 mg/lb) body weight. Administer once daily for osteoarthritis. Administer approximately 2 hours before soft tissue or orthopedic surgery.

(ii) Indications for use. For the control of pain and inflammation associated with osteoarthritis; and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Horses--(i) Amount. Administer one 57-mg tablet to horses weighing 800 to 1,300 lb once daily for up to 14 days.

(ii) Indications for use. For the control of pain and inflammation associated with osteoarthritis.

(iii) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2345c [Amended]

5. In § 520.2345c, remove paragraph (d)(1)(iii).

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

6. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

7. Add § 522.224 to read as follows:

§ 522.224 Bupivacaine.

(a) Specifications. Each milliliter (mL) of liposomal suspension contains 13.3 milligrams (mg) bupivacaine.

(b) Sponsor. See No. 086026 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs--(1) Amount. Administer 5.3 mg/kg (0.4 mL/kg) by infiltration injection into the tissue layers at the time of incisional closure.

(2) Indications for use. For single-dose infiltration into the surgical site to provide local postoperative analgesia for cranial cruciate ligament surgery in dogs.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

8. In § 522.1870, revise paragraphs (a), (c)(1)(i) and (iii), and (c)(2)(i) and (iii) to read as follows:

§ 522.1870 Praziquantel.

(a) Specifications. Each milliliter (mL) of solution contains 56.8 milligrams of praziquantel.

* * * * *

(c) * * *

(1) * * *

(i) Amount. Administer by subcutaneous or intramuscular injection for dogs and puppies 5 pounds (lb) and under, 0.3 mL; for 6 to 10 lb, 0.5 mL; for 11 to 25 lb, 1.0 mL; if over 25 lb, 0.2 mL/5 lb body weight to a maximum of 3 mL.

* * * * *

(iii) Limitations. Federal law restricts the drug to use by or on the order of a licensed veterinarian.

(2) * * *

(i) Amount. Administer by subcutaneous or intramuscular injection for cats and kittens under 5 lb, 0.2 mL; 5 to 10 lb, 0.4 mL; 11 lb and over, 0.6 mL maximum.

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(iii) Limitations. Federal law restricts the drug to use by or on the order of a licensed veterinarian.

9. In § 522.2630, revise paragraph (d)(1)(iii)(A) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(A) Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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10. Revise § 522.2640 to read as follows:

§ 522.2640 Tylosin.

(a) Specifications. Each milliliter (mL) of solution contains 50 or 200 milligrams (mg) of tylosin activity (as tylosin base).

(b) Sponsors. See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 000986 for use of 50- or 200-mg/mL solutions as in paragraph (e) of this section.

(2) Nos. 000010 and 061623 for use of a 200-mg/mL solution as in paragraphs (e)(1) and (2) of this section.

(c) Related tolerances. See § 556.740 of this chapter.

(d) Special considerations. Labeling must bear the warning statements: "Do not administer to horses or other equines. Injection of tylosin in equines has been fatal."

(e) Conditions of use--(1) Beef cattle and nonlactating dairy cattle--(i) Amount. Administer 8 mg per pound (mg/lb) of body weight by intramuscular injection once daily for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear.

(ii) Indications for use. Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with Pasteurella multocida and Arcanobacterium pyogenes; foot rot (necrotic pododermatitis) and calf diphtheria caused by Fusobacterium necrophorum and metritis caused by A. pyogenes.

(iii) Limitations. Do not inject more than 10 mL per site. Use a 50-mg/mL solution for calves weighing less than 200 pounds. Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use

in these cattle may cause drug residues in milk and/or in calves born to these cows. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves.

(2) Swine--(i) Amount. Administer 4 mg/lb of body weight by intramuscular injection twice daily for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. If tylosin medicated drinking water is used as a followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

(ii) Indications for use. Treatment of swine arthritis caused by Mycoplasma hyosynoviae; swine pneumonia caused by Pasteurella spp.; swine erysipelas caused by Erysipelothrix rhusiopathiae; swine dysentery associated with Treponema hyodysenteriae when followed by appropriate medication in the drinking water and/or feed.

(iii) Limitations. Do not inject more than 5 mL per site. Adverse reactions, including shock and death may result from overdosage in baby pigs. It is recommended that tylosin 50-mg/mL injection be used in pigs weighing less than 25 lbs. Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product.

(3) Dogs and cats--(i) Amount. Administer 3 to 5 mg/lb of body weight by intramuscular injection at 12- to 24-hour intervals.

(ii) Indications for use--(A) Dogs. Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by Staphylococci spp., hemolytic Streptococci spp., and Pasteurella multocida.

(B) Cats. Treatment of upper respiratory infections when caused by Staphylococci spp. and hemolytic Streptococci spp. and for feline pneumonitis when caused by tylosin-susceptible organisms.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

11. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

12. Add § 524.998 to read as follows:

§ 524.998 Fluralaner.

(a) Specifications. Each milliliter of solution contains 280 milligrams (mg) fluralaner.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Conditions of use--(1) Dogs--(i) Amount. Administer topically as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 11.4 mg/lb (25 mg/ kg) body weight. May be administered every 8 weeks in case of potential exposure to Amblyomma americanum ticks.

(ii) Indications for use. Kills adult fleas; for the treatment and prevention of flea infestations (Ctenocephalides felis) and the treatment and control of tick infestations (Ixodes scapularis (black-legged tick), Dermacentor variabilis (American dog tick), and Rhipicephalus sanguineus (brown dog tick)) for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater; for the treatment and control of A. americanum (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

13. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.400 [Amended]

14. In § 529.400, in paragraph (a), remove footnote 1.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

15. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

§ 558.58 [Amended]

16. In § 558.58, in paragraph (e)(6), remove "3.6" and in its place add "36.6".

17. Revise § 558.59 to read as follows:

§ 558.59 Apramycin.

(a) Specifications. Each pound of Type A article contains 75 grams apramycin (as apramycin sulfate).

(b) Sponsor. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) Related tolerances. See § 556.52 of this chapter.

(e) Conditions of use in swine--(1) Amount. Feed at 150 grams apramycin per ton of Type C medicated feed as the sole ration for 14 consecutive days.

(2) Indications for use. For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of Escherichia coli.

(3) Limitations. Withdraw 28 days before slaughter.

§ 558.68 [Amended]

18. In § 558.68, redesignate paragraphs (c) and (d) as paragraphs (d) and (c); and in paragraphs (e)(1)(i) and (e)(2)(i), remove "000986" and in its place add "058198".

§ 558.128 [Amended]

19. In § 558.128, in paragraph (e)(7)(xi), remove "§ 558.600" and in its place add ″§ 558.612″.

§ 558.195 [Amended]

20. In § 558.195, in paragraph (e)(1)(vi), remove "000009" and in its place add "054771"; and in paragraphs (e)(2)(iii) and (v), remove "000986" wherever it appears and in its place add "058198".

§ 558.261 [Amended]

21. In § 558.261, redesignate paragraphs (c) and (d) as paragraphs (d) and (c).

§ 558.295 [Amended]

22. In § 558.295, remove and reserve paragraph (b).

23. In § 558.325, revise paragraph (d)(3) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(d) * * *

(3) Labeling of Type A medicated articles and single-ingredient Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following caution

statement: "The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been determined. Not for use in swine intended for breeding when lincomycin is fed at 20 grams per ton of complete feed."

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§ 558.342 [Amended]

24. In § 558.342, in paragraphs (e)(1)(iv),(ix), (x), and (xi), remove "000986" wherever it appears and in its place add "058198".

§ 558.366 [Amended]

25. In § 558.366, in paragraph (d), in the entry for "113.5 (0.0125 pct)", remove "000986" and in its place add "058198".

§ 558.618 [Amended]

26. In § 558.618, redesignate paragraphs (c) and (d) as paragraphs (d) and (c).

27. In § 558.633, revise paragraph (d)(1) to read as follows:

§ 558.633 Tylvalocin.

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(d) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

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Dated: September 21, 2016.

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